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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,637	04/30/2001	Michael C. Jensen	24751-2502	4845

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/23/2003

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~~Please find below and/or attached an Office communication concerning this application or proceeding.~~

Office Action Summary

Application No.

09/846,637

Applicant(s)

JENSEN, MICHAEL C.

Examiner

Yong D Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41, 48, 50-54, 63, 73, 74, 81, 82, 85, 141-143 and 166-269 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 73-74, 142-143, 190-191, 206-207, 219-220, 234-235, 248-249, and 260-261 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims rejected are 23-41,48,50-54,63,81-82,85,141,166-189,192-205,208-218,221-233,236-247,250-259 and 262-269.

DETAILED ACTION

The amendment filed on December 6, 2001, canceling claims 4-7, 13-21 and 23-49, amending claims 1-3, 5, 8-9 and 22 and adding claims 50-54, has been entered.

Claims 1-3, 5, 8-12, 22 and 50-54 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-41, 48, 50-54, 63, 81-82, 85, 141, 143, 166-189, 192-205, 208-218, 221-233, 236-248, 250-259 and 262-269 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farazi et al. in view of Roelant.

Farazi et al. (form PTO-892) teach mutants of human IMPDH type II that are resistant to inhibitors of wildtype IMPDH (abstract and page 961). Farazi et al. teach that inhibitors of IMPDH have antiproliferative activity (page 961). Farazi et al. teach that MPA, MPA derivatives and mycophenolate mofetil are specific inhibitors of IMPDH (page 961). Farazi et al. teach that mutant IMPDH confers resistance to and is very

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useful in anti-infective chemotherapy by designing species-selective IMPDH inhibitors and anti-infective chemotherapy (page 961). It is well known in the art that tiazofurin, ribavirin and mizoribine are inhibitors of IMPDH (Krystek et al., Column 1 [0006]).

In the state of the art, there are many methods thought which one can ascertain the result of a mutagenized enzyme. One way is to perform cell proliferation assays since inhibitors of IMPDH have antiproliferative activity where resistance against the inhibitors of IMPDH corresponds to an increase in the proliferation of the cells

containing the mutant IMPDH.

The difference between the instant invention and the reference of Farazi et al. is that the reference of Farazi et al. does not teach cell proliferation assays.

Cell proliferation assays are well known in the art. Roelant et al. (U.S. Patent No. 5,306,624) teach how to perform proliferation assay by quantifying the number of viable cells (abstract and claims). Stratagene is one of many companies that teach how to perform cell proliferation assays (from PTO-892).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the mutant of Farazi et al. and screen whether the mutants have resistance against inhibitors of IMPDH by performing cell proliferation assays, quantifying viable cells containing the mutant enzymes and cell containing wildtype IMPDH. The motivation of performing the cell proliferation assay is to determine if the mutant IMPDH are resistant to IMPDH inhibitors since inhibition of IMPDH results in anti-proliferative activity. Also, IMPDH that are resistant to its inhibitors can be useful in anti-infective chemotherapy by designing species-selective

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IMPDH inhibitors. One of ordinary skill in the art would have had a reasonable expectation of success since Farazi et al. teach mutant IMPDH that is resistant against its inhibitors and cell proliferation assays are performed routinely in the art.

Allowable Subject Matter

Claims 73-74, 142-143, 190-191, 206-207, 219-220, 234-235, 248-249, and 260-261 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner

September 22, 2003



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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